MAR 13 2012

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is k103116

1. Submitter's Identification

Bestgen Biotech Corporation
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2. Device Name

Proprietary name: AP-2000, AP-2000multi, AP-2010, AP-2010multi, AP-2020, and AP-2020multi Blood Glucose Monitoring System

Regulatory information:

A. Regulation section:	21 CFR Section 862.1345 Glucose Test System 21 CFR Section 862.1660, Quality Control Material
B Classification:	Class II for 862.1345 Class I for 862.1660
C. Product Code:	CGA, Glucose Oxidase, Glucose NBW, System, Test, Blood Glucose, Over The Counter JJX, Quality Control Material (assayed and unassayed)
D. Panel:	Chemistry (75)

3. Intended Use

3.1 AP-2000 Blood Glucose Monitoring System

The AP-2000 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The AP-2000 Blood Glucose Monitoring Systems is intended for testing outside the body (in vitro diagnostic use). It is indicated for use at home (over the counter) [OTC] by a single patient with diabetes and should not be shared, as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-2000 Meter is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. AP-2000 Blood Glucose Test Strips must be used with the AP-2000 Meter. It is indicated for use at home (over the counter) [OTC] by a single patient with diabetes and should not be shared, as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for

diabetes mellitus, and is not intended for use on neonates.

The AP-2000 Blood Glucose Test Strips are intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. AP-2000 Blood Glucose Test Strips must be used the AP-2000 Blood Glucose Meter. It is indicated for use at home (over the counter) [OTC] by a single patient with diabetes and should not be shared, as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

MAJOR Level I/Level II Control Solution are for use with AP-2000 meter and AP-2000 Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results.

3.2 AP-2000multi Blood Glucose Monitoring System

The AP-2000multi Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The AP-2000multi Blood Glucose Monitoring Systems is intended for testing outside the body (in vitro diagnostic use). It is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use, auto-disabling lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-2000multi Meter is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. AP-2000multi Blood Glucose Test Strips must be used with the AP-2000multi Meter. It is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use, auto-disabling lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-2000multi Blood Glucose Test Strips are intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. AP-2000multi Blood Glucose Test Strips must be used the AP-2000multi Blood Glucose Meter. It is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use, auto-disabling lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

MAJOR Level I/Level II Control Solution is for use with AP-2000multi meter and AP-2000multi Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results.

3.3 AP-2010 Blood Glucose Monitoring System

The AP-2010 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The AP-2010 Blood Glucose Monitoring Systems is intended for testing outside the body (in vitro diagnostic use). It is indicated for use at home (over the counter) [OTC] by a single patient with diabetes and should not be shared, as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-2010 Meter is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. AP-2010 Blood Glucose Test Strips must be used with the AP-2010 Meter. It is indicated for use at home (over the counter) [OTC] by a single patient with diabetes and should not be shared, as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-2010 Blood Glucose Test Strips are intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. AP-2010 Blood Glucose Test Strips must be used the AP-2010 Blood Glucose Meter. It is indicated for use at home (over the counter) [OTC] by a single patient with diabetes and should not be shared, as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

MAJOR Level I/Level II Control Solution are for use with AP-2010 meter and AP-2010 Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results.

3.4 AP-2010multi Blood Glucose Monitoring System

The AP-2010multi Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The AP-2010multi Blood Glucose Monitoring Systems is intended for testing outside the body (in vitro diagnostic use). It is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use, auto-disabling lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-2010multi Meter is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. AP-2010multi Blood Glucose Test Strips must be used with the AP-2010multi Meter. It is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use, auto-disabling lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-2010multi Blood Glucose Test Strips are intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. AP-2010multi Blood Glucose Test Strips must be used the AP-2010multi Blood Glucose Meter. It is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use, auto-disabling lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

MAJOR Level I/Level II Control Solution is for use with AP-2010multi meter and AP-2010multi Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results.

3.5 AP-2020 Blood Glucose Monitoring System

The AP-2020 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The AP-2020 Blood Glucose Monitoring Systems is intended for testing outside the body (in vitro diagnostic use). It is indicated for use at home (over the counter) [OTC] by a single patient with diabetes and should not be shared, as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-2020 Meter is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. AP-2020 Blood Glucose Test Strips must be used with the AP-2020 Meter. It is indicated for use at home (over the counter) [OTC] by a single patient with diabetes and should not be shared, as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-2020 Blood Glucose Test Strips are intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. AP-2020 Blood Glucose Test Strips must be used the AP-2020 Blood Glucose Meter. It is indicated for use at home (over the counter) [OTC] by a single patient with diabetes and should not be shared, as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

MAJOR Level I/Level II Control Solution are for use with AP-2020 meter and AP-2020 Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results.

3.6 AP-2020multi Blood Glucose Monitoring System

The AP-2020multi Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The AP-2020multi Blood Glucose Monitoring Systems is intended for testing outside the body (in vitro diagnostic use). It is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use, auto-disabling lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-2020multi Meter is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. AP-2020multi Blood Glucose Test Strips must be used with the AP-2020multi Meter. It is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use, auto-disabling lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-2020multi Blood Glucose Test Strips are intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. AP-2020multi Blood Glucose Test Strips must be used the AP-2020multi Blood Glucose Meter. It is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use, auto-disabling lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

MAJOR Level I/Level II Control Solution is for use with AP-2020multi meter and AP-2020multi Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results.

4. Device Description

The AP-2000 Blood Glucose Monitoring System consists of three main products: the meter, test strip, and control solutions. These products have been designed, tested, and proven to work together as a system accurate blood glucose test results. Use only AP-2000 test strips and MAJOR control solution with the AP-2000 Blood Glucose Monitoring System.

The AP-2010multi Blood Glucose Monitoring System consists of three main products: the meter, test strip, and control solutions. These products have been designed, tested, and proven to work together as a system accurate blood glucose test results. Use only AP-2010multi test strips and MAJOR control solution with the AP-2010multi Blood Glucose Monitoring System.

The AP-2010 Blood Glucose Monitoring System consists of three main products: the meter, test strip, and control solutions. These products have been designed, tested, and proven to work together as a system accurate blood glucose test results. Use only AP-2010 test strips and MAJOR control solution with the AP-2010 Blood Glucose Monitoring System.

The AP-2010multi Blood Glucose Monitoring System consists of three main products: the meter, test strip, and control solutions. These products have been designed, tested, and proven to work together as a system accurate blood glucose test results. Use only AP-2010multi test strips and MAJOR control solution with the AP-2010multi Blood Glucose Monitoring System.

The AP-2020 Blood Glucose Monitoring System consists of three main products: the meter, test strip, and control solutions. These products have been designed, tested, and proven to work together as a system accurate blood glucose test results. Use only AP-2020 test strips and MAJOR control solution with the AP-2020 Blood Glucose Monitoring System.

The AP-2020multi Blood Glucose Monitoring System consists of three main products: the meter, test strip, and control solutions. These products have been designed, tested, and proven to work together as a system accurate blood glucose test results. Use only AP-2020multi test strips and MAJOR control solution with the AP-2020multi Blood Glucose Monitoring System.

5. Substantial Equivalence Information

A. Predicate device name:
AP-1000 Blood Glucose Monitoring System

B. Predicate K number: k090389

C. Comparison with predicate:
The modified AP-2000, AP-2000multi, AP-2010, AP-2010multi, AP-2020, and AP-2020multi Blood Glucose Monitoring System have the following similarities to the predicate device:

- same operating principle,
- same fundamental scientific technology,
- incorporate the same basic circuit design,
- incorporate the same materials,

- same shelf life
- packaged using the same materials, and
- manufactured by same process

The modifications encompass:

- engineering change in the mechanical appearance of the device and name change
- different power source-batteries and software change
- the printed circuit board (PCB) was changed
- the software was modified
- the addition of a speaking function

6. Test Principle

The detection and measurement of glucose in blood is by an electrochemical biosensor technology using glucose oxidase.

7. Performance Characteristics

AP-2000, AP-2000multi, AP-2010, AP-2010multi, AP-2020, and AP-2020multi Blood Glucose Monitoring System has the same performance characteristics as the predicate device.

A comparison of system accuracy performance demonstrated that AP-2000, AP-2000multi, AP-2010, AP-2010multi, AP-2020, and AP-2020multi Blood Glucose Monitoring System and the currently marketed AP-2000, AP-2000multi, AP-2010, AP-2010multi, AP-2020, and AP-2020multi Blood Glucose Monitoring System are substantially equivalent.

Software verification and validation testing confirmed that the performance, safety and effectiveness of the AP-2000, AP-2000multi, AP-2010, AP-2010multi, AP-2020, and AP-2020multi Blood Glucose Monitoring System are equivalent to the predicate device.

8. Conclusion

Based on the information provided in this submission, the AP-2000, AP-2000multi, AP-2010, AP-2010multi, AP-2020, and AP-2020multi Blood Glucose Monitoring System is substantially equivalent to the predicate AP-1000 Blood Glucose Monitoring System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Bestgen Biotech Corp.
c/o Steven Shen
Q.A./Regulatory Affairs Manager
7f, No 186, Jian-Yi Road,
Jung-He, Taipei County
China (TAIWAN) 235

MAR 13 2012

Re: k103116
Trade Name: AP-2000/AP-2000multi, AP-2010/AP-2010multi, and AP-2020/AP-2020multi Blood Glucose Monitoring Systems
Regulation Number: 21 CFR 862.1345
Regulation Name:Glucose test system.
Regulatory Class: II
Product Code: NBW, CGA, JJX
Dated: February 23, 2012
Received: March 2, 2012

Dear Mr. Shen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: k103116

Device Name: AP-2000 Blood Glucose Monitoring System

Indications for Use:

The AP-2000 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The AP-2000 Blood Glucose Monitoring Systems is intended for testing outside the body (in vitro diagnostic use). It is indicated for use at home (over the counter) [OTC] by a single patient with diabetes and should not be shared, as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-2000 Meter is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. AP-2000 Blood Glucose Test Strips must be used with the AP-2000 Meter. It is indicated for use at home (over the counter) [OTC] by a single patient with diabetes and should not be shared, as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-2000 Blood Glucose Test Strips are intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. AP-2000 Blood Glucose Test Strips must be used the AP-2000 Blood Glucose Meter. It is indicated for use at home (over the counter) [OTC] by a single patient with diabetes and should not be shared, as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

MAJOR Level I/Level II Control Solution are for use with AP-2000 meter and AP-2000 Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results.

Prescription Use_____ And/Or Over the Counter Use__V__

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Ruth Chesler

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k103116

Indications for Use

510(k) Number: k103116

Device Name: AP-2000multi Blood Glucose Monitoring System

Indications for Use:

The AP-2000multi Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The AP-2000multi Blood Glucose Monitoring Systems is intended for testing outside the body (in vitro diagnostic use). It is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use, auto-disabling lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-2000multi Meter is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. AP-2000multi Blood Glucose Test Strips must be used with the AP-2000multi Meter. It is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use, auto-disabling lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-2000multi Blood Glucose Test Strips are intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. AP-2000multi Blood Glucose Test Strips must be used the AP-2000multi Blood Glucose Meter. It is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use, auto-disabling lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

MAJOR Level I/Level II Control Solution is for use with AP-2000multi meter and AP-2000multi Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results.

Prescription Use V (21 CFR Part 801 Subpart D) And/Or Over the Counter Use V (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Ruth Chaln

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k103116

Indications for Use

510(k) Number: k103116

Device Name: AP-2010 Blood Glucose Monitoring System

Indications for Use:

The AP-2010 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The AP-2010 Blood Glucose Monitoring Systems is intended for testing outside the body (in vitro diagnostic use). It is indicated for use at home (over the counter) [OTC] by a single patient with diabetes and should not be shared, as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-2010 Meter is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. AP-2010 Blood Glucose Test Strips must be used with the AP-2010 Meter. It is indicated for use at home (over the counter) [OTC] by a single patient with diabetes and should not be shared, as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-2010 Blood Glucose Test Strips are intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. AP-2010 Blood Glucose Test Strips must be used the AP-2010 Blood Glucose Meter. It is indicated for use at home (over the counter) [OTC] by a single patient with diabetes and should not be shared, as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

MAJOR Level I/Level II Control Solution are for use with AP-2010 meter and AP-2010 Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results.

Prescription Use_____ And/Or Over the Counter Use__V__

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k103116

Indications for Use

510(k) Number: k103116

Device Name: AP-2010multi Blood Glucose Monitoring System

Indications for Use:

The AP-2010multi Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The AP-2010multi Blood Glucose Monitoring Systems is intended for testing outside the body (in vitro diagnostic use). It is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use, auto-disabling lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-2010multi Meter is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. AP-2010multi Blood Glucose Test Strips must be used with the AP-2010multi Meter. It is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use, auto-disabling lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-2010multi Blood Glucose Test Strips are intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. AP-2010multi Blood Glucose Test Strips must be used the AP-2010multi Blood Glucose Meter. It is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use, auto-disabling lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

MAJOR Level I/Level II Control Solution is for use with AP-2010multi meter and AP-2010multi Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results.

Prescription Use V And/Or Over the Counter Use V

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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Evaluation and Safety

510(k) k103116

Indications for Use

510(k) Number: k103116

Device Name: AP-2020 Blood Glucose Monitoring System

Indications for Use:

The AP-2020 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The AP-2020 Blood Glucose Monitoring Systems is intended for testing outside the body (in vitro diagnostic use). It is indicated for use at home (over the counter) [OTC] by a single patient with diabetes and should not be shared, as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-2020 Meter is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. AP-2020 Blood Glucose Test Strips must be used with the AP-2020 Meter. It is indicated for use at home (over the counter) [OTC] by a single patient with diabetes and should not be shared, as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-2020 Blood Glucose Test Strips are intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. AP-2020 Blood Glucose Test Strips must be used the AP-2020 Blood Glucose Meter. It is indicated for use at home (over the counter) [OTC] by a single patient with diabetes and should not be shared, as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

MAJOR Level I/Level II Control Solution are for use with AP-2020 meter and AP-2020 Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results.

Prescription Use_____ And/Or Over the Counter Use__V__

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Indications for Use

510(k) Number: k103116

Device Name: AP-2020multi Blood Glucose Monitoring System

Indications for Use:

The AP-2020multi Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The AP-2020multi Blood Glucose Monitoring Systems is intended for testing outside the body (in vitro diagnostic use). It is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use, auto-disabling lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-2020multi Meter is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. AP-2020multi Blood Glucose Test Strips must be used with the AP-2020multi Meter. It is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use, auto-disabling lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-2020multi Blood Glucose Test Strips are intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger. AP-2020multi Blood Glucose Test Strips must be used the AP-2020multi Blood Glucose Meter. It is intended for multi-patient use in a professional healthcare setting, as an aid to monitor the effectiveness of diabetes control. The system is only used with single-use, auto-disabling lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

MAJOR Level I/Level II Control Solution is for use with AP-2020multi meter and AP-2020multi Blood Glucose Test Strips as a quality control check to verify the accuracy of blood glucose test results.

Prescription Use V (21 CFR Part 801 Subpart D) And/Or Over the Counter Use V (21 CFR Part 801 Subpart C)

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